This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

F. Johnson 11/21/05

Interagency Report Control No.: 11

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 74-R-0012
CUSTOMER NUMBER: 1499

FORM APPROVED
OMB NO. 0579-0036

"A" by D. Jones 12/29/06

Texas A&M University
Lab Animal Resources & Research
Office Of Research Compliance
1186 Tamu
College Station, TX 77843

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (**Attach additional sheets if necessary or use APHIS Form 7023A**)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		9	246		255
5. Cats					
6. Guinea Pigs		890		10	900
7. Hamsters					
8. Rabbits		408			408
9. Non-human Primates					
10. Sheep	92	16	46		~~154~~ 62
11. Pigs	76		43		~~119~~ 43
12. Other Farm Animals					
Cattle	3	15	29		~~47~~ 44
13. Other Animals					
Bats		65			65
Ferrets		3		17	20

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

DATE SIGNED
11/17/05

NOV 18 2005

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

COPY FOR YOUR INFORMATION

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F TOTAL NO. OF ANIMALS (Cols. C + D + E)
Goats	20		41		~~61~~ 41
Horses		22			22
Red Sheep	4				~~4~~ 0
Iranian Sheep		3			3
Fallow Deer	26				~~26~~ 0
Red Deer		95			95

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)c		11/17/05

HEADQUARTERS
NOV 18 2005

Registration Number: 74-R-0012
Customer Number: 1499

Texas A&M University
USDA Site Designations

SITE NAME
(b)(2)High, (b)(7)f

Column E. Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 74-R-0012

2. **Number** 10 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in the study.**

4. **Explain the procedure producing pain and/or distress.**

This project is to test an influenza nasal powder vaccine incorporating a novel *insitu* gelling nasal delivery system (GelVac™). This vaccine, with either avian influenza H5 antigen or current human trivalent influenza vaccine antigens (H1N1, H3N2 and B), is given as a spray of powder in the nose rather than the usual shot. The GelVac powder containing a unique carbohydrate polymer (GelSite) forms a gel layer upon contact with secretions in the nose, and prolongs the vaccine residence in that location for an efficient antigen uptake. This three-year study is designed to 1) test various powder vaccine formulations and 2) determine if the vaccine will produce strong immune responses and protect against infection with influenza.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)**

Ferrets produce antibodies to influenza virus infection, show a nasal cellular response to the virus and exhibit a fever response when infected. They make very specific antibody to various strains of influenza virus and are routinely used to produce reference antisera. The natural disease course has to be followed for the data to be meaningful during the challenge experiment. A good correlation between data generated in ferrets and vaccine performance in humans does exist with Ljungberg (Vaccine 2002), JJ Donnelly (Vaccine 1997) and the Centers for Disease and Prevention (LA Zitzow, 2002, J Vir), and also by the latest publications found in PubMed, including Lee and Chen (Emerg Infect Dis, 2004) and Lambkin et al (Vaccine, 2004).
The search for replacement and refinement did not yield any alternatives for the animal models used in influenza virus research.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**

Column E. Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 74-R-0012

2. Number 17 **of animals used in this study.**

3. Species (common name) Ferrets **of animals used in the study.**

4. Explain the procedure producing pain and/or distress.

This project is to test an influenza nasal powder vaccine incorporating a novel *insitu* gelling nasal delivery system (GelVac™). This vaccine, with either avian influenza H5 antigen or current human trivalent influenza vaccine antigens (H1N1, H3N2 and B), is given as a spray of powder in the nose rather than the usual shot. The GelVac powder containing a unique carbohydrate polymer (GelSite) forms a gel layer upon contact with secretions in the nose, and prolongs the vaccine residence in that location for an efficient antigen uptake. This three-year study is designed to 1) test various powder vaccine formulations and 2) determine if the vaccine will produce strong immune responses and protect against infection with influenza.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Ferrets produce antibodies to influenza virus infection, show a nasal cellular response to the virus and exhibit a fever response when infected. They make very specific antibody to various strains of influenza virus and are routinely used to produce reference antisera. The natural disease course has to be followed for the data to be meaningful during the challenge experiment. A good correlation between data generated in ferrets and vaccine performance in humans does exist with Ljungberg (Vaccine 2002), JJ Donnelly (Vaccine 1997) and the Centers for Disease and Prevention (LA Zitzow, 2002, J Vir), and also by the latest publications found in PubMed, including Lee and Chen (Emerg Infect Dis, 2004) and Lambkin et al (Vaccine, 2004).
The search for replacement and refinement did not yield any alternatives for the animal models used in influenza virus research.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)

TEXAS A&M UNIVERSITY

(b)(2)High, (b)(7)f

College Station, Texas 77845-1186

(b)(2)High, (b)(7)f Fax: (979) 862-3176

DATE: December 15, 2005

TO: Linda Kovar, USDA

FAX NUMBER: 970-494-7461

DESCRIPTION: Corrected 2005 APHIS Report

FROM: (b)(6), (b)(7)c

PAGES SENT (Including Cover Page): 4

Hi Linda,
Happy Holidays! Thanks for contacting me regarding the 2005 APHIS report. Attached are the corrected totals, which now reflect columns C, D and E only. Also, attached is the Category E rationale for use of Guinea Pigs. I can be reached at (b)(2)High, (b)(7)f **if you need any additional information.**

Thanks again!
(b)(6), (b)(7)c

SHOULD YOU EXPERIENCE ANY DIFFICULTIES IN RECEIVING THIS FACSIMILE, PLEASE CALL THE OFFICE AT (979) 458-4067.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 74-R-0012
CUSTOMER NUMBER: 1499

FORM APPROVED
OMB NO. 0579-0036

Texas A&M University
Lab Animal Resources & Research
Office Of Research Compliance
1186 Tamu
College Station, TX 77843

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		9	246		255
5. Cats					
6. Guinea Pigs		890		10	900
7. Hamsters					
8. Rabbits		408			408
9. Non-human Primates					
10. Sheep	92	16	46		62
11. Pigs	76		43		43
12. Other Farm Animals					
Cattle	3	15	29		44
13. Other Animals					
Bats		65			65
Ferrets		3		17	20

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesteic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

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4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
	[redacted] ch	

(b)(6), (b)(7)c

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obs
(AUG 91)

[redacted]

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
Goats	20		41		41
Horses		22			22
Red Sheep	4				0
Iranian Sheep		3			3
Fallow Deer	26				0
Red Deer		95			95

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
	(b)(6), (b)(7)c	

APHIS FORM 7023A
(AUG 91)

PART 1 - HEADQUARTERS

DEC 15 2005

Column E. Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 74-R-0012

2. **Number** 10 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in the study.**

4. **Explain the procedure producing pain and/or distress.**

The purpose of this study is to develop and characterize an aerosol challenge model of acute Q fever in guinea pigs. The determination of infecting dose and expected clinical illness associated with each dose is necessary to choose a dose, reliably causing fever but not severe morbidity, to be used in future studies evaluating the efficacy of vaccines and treatment regimes.
The procedure with the potential to cause pain and distress in the guinea pigs is infection with *Coxiella burnetii*. Infected animals will develop a fever, the primary indicator of Q fever infection in this species, and at higher doses may experience inappetence and lethargy.
Infected guinea pigs developed various degrees of fever depending on the dose of organisms delivered. At the highest dose, guinea pigs experienced temperatures in excess of 40°C, inappetence, lethargy, and morbidity such that euthanasia was elected.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)**

Intervention with analgesics is likely to alter the course of disease. Analgesics may affect the validity of the fever response measurements, the main disease indicator in guinea pigs. Therefore, analgesics are inappropriate for these experiments.
Relief was given to animals exhibiting dehydration during the febrile stage of illness by administration of sterile 0.9% NaCL SQ in amounts and frequency as deemed appropriate by the attending veterinarian.
Humane euthanasia was elected for moribund animals or those with excessive weight loss or respiratory disease as indicated by a modified Karnofsky's scale.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**